



STANDARD OPERATING GUIDELINES: EVIDENTIAL BREATH ALCOHOL INSTRUMENT CALIBRATION

1 Scope

To describe the procedure for breath alcohol instrument calibration and the calculations used to establish the combined uncertainty.

Any changes which occur as a result of the implementation of these Guidelines apply only to breath tests that are done on or after the effective date of this document. These procedures were adapted for accreditation purposes from those previously determined by the Scientific Director to be valid for use. Previous policies are not nullified and nothing herein should be construed as limiting or canceling the effect of old policies on tests done under these previous policies.

2 Calibration Terms

2.1 Definitions

Accuracy – A qualitative term describing the closeness of agreement between measured quantity value and a true quantity value of a measurand.

Adjustment – A set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of the quantity to be measured.

Air-liquid partition constant – A constant used to determine the vapor ethanol concentration above an ethanol and water solution. For a 34°C solution of ethanol and water, the vapor concentration in g/210 L is determined by dividing the liquid concentration in g/100 mL by 1.23.

Analyst – One who, in addition to performing tests and calibrations, interprets data, conducts technical and administrative reviews, reaches conclusions and authorizes the release of a calibration certificate, report or label. A Technical Supervisor is an analyst.

Bias – The quantitative measure of accuracy also referred to as the systematic error.

Calibration – A procedure that establishes the accuracy, precision, uncertainty of measurement and linear response of a breath alcohol measuring instrument by the measurement of known standards. It is not defined as any other action to repair, adjust, clean, autocal or test an instrument. These actions are maintenance and are not part of the calibration procedure.

Certified Reference Material (CRM) – Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Combined uncertainty – The standard deviation of the result of a measurement when the result is obtained from the values of a number of other quantities. It is obtained by combining the individual standard uncertainties using the "root-sum-of-squares" method. Combined uncertainty shall be reported at approximately the 99.7% level ($k = 3$) to four digits (rounded) after the decimal point.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 2 of 19

Confidence level – Number (e.g. 99.7%) expressing the degree of confidence in a result.

Lot – A large volume of ethanol reference material that is mixed in a single container and considered to be uniform in ethanol concentration once the material is divided into smaller containers.

Lot number – A unique designator to document the preparation, analysis and traceability of a reference material or standard.

Mean – The average of a set of numbers that shall be reported to four digits (rounded) after the decimal point. Example: 0.0802 g/210 L

Measurand – Particular quantity intended to be measured.

Nominal value – The rounded or approximate value of a characterizing quantity of a measuring instrument or measuring system that provides guidance for its appropriate use. The nominal value of a Solution Lot shall be reported to three digits after the decimal point. Example: 0.080 g/210 L

Nominal vapor concentration – The named or target value of a Solution Lot, also known as the predicted value and the nominal value. The nominal vapor concentration of a Solution Lot shall be reported to three digits after the decimal point. Example: 0.080 g/210 L

Office of the Scientific Director – The entity created by the Texas Department of Public Safety to carry out the provisions of Texas Administrative Code Title 37 Chapter 19 Breath Alcohol Testing Regulations. The Office of the Scientific Director provides certified reference materials and approves calibration procedures for forensic breath alcohol testing instruments.

Precision – The degree to which replicate measurement results agree amongst themselves, most commonly quantified by the standard deviation.

Purified water – Water purified by any scientifically acceptable means including, but not limited to filtration, deionization, distillation, or reverse osmosis.

Pure ethanol – An ethanol reagent that is certified by the manufacturer to contain at least 99.5% ethanol.

Repeatability – Closeness of the agreement between repeated measurements of the same property with the same methods, on identical test items, in the same lab, by the same analyst using the same equipment, in a short time interval.

Reference material – A homogenous and stable material sufficiently characterized with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Simulator – A device designed to heat an aqueous solution to a known temperature, used to deliver a vapor sample, usually ethanol, to a breath alcohol testing instrument for the purposes of calibration, calibration adjustment and/or calibration verification.

Standard – A reference material accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.



Standard deviation – A measure of the spread of a set of results, describing how values typically differ from the average of the set.

Systematic error – A measurement error or bias due to fixed or constant sources that are the same in magnitude and direction for all measurements.

Technical Supervisor – A forensic scientist certified by the Office of the Scientific Director pursuant to the provisions of Texas Administrative Code Title 37 Chapter 19. A certified technical supervisor authorized to perform work in the calibration laboratory is by definition a calibration and reviewing analyst.

Traceability – The property of a measurement result whereby it can be related to a national authoritative standard through an unbroken chain of comparisons with each level having estimated uncertainties.

True value – The value that would be obtained by a theoretical perfect measurement.

Uncertainty budget – Summary of the combined uncertainty calculations including a listing of all factors that contribute to the overall uncertainty measurement for a process.

Uncertainty of measurement – An estimate of the range of values most likely to contain the measured quantity.

Vapor concentration – The ethanol concentration in the headspace above a dilute ethanol aqueous solution held at a known temperature, expressed in g/210 L.

2.2 Abbreviations

C	Concentration
COA	Certificate of Analysis
Comb	Combined
CRM	Certified Reference Material (simulator solution)
CRS	Certified Reference Standard
CV	Coefficient of Variation
Intox	Intoxilyzer
Lot	CRM solution lot
NIST	United States National Institute of Standards and Technology
OSD	Office of the Scientific Director
SD	Standard deviation
VC	Vapor concentration

3 Breath Alcohol Instrument Calibration Procedure

3.1 General

- A. For the purposes of this document, calibration is defined as a procedure that establishes the accuracy, precision, uncertainty of measurement and linear response of a breath alcohol measuring instrument by the measurement of known standards. It is not defined as any other action to repair, adjust, clean,



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 4 of 19

autocal or test an instrument. These actions are maintenance and are not part of the calibration procedure.

- B. Instruments are to be calibrated only by certified Technical Supervisors in the Technical Supervisor's laboratory which has limited access. Handling and storage of instruments while in the laboratory shall be exercised with care in order to preserve their scientific integrity.
- C. If the Technical Supervisor determines that an environmental or other condition might affect the quality of the calibration, the procedure shall be terminated and not resumed until the cause for concern has been eliminated.

3.2 Documentation

- A. When received into the calibration laboratory, in no particular order, the Calibration Analyst shall note the following on the Instrument Receipt and Condition Notes label (OSD-CAL-02). The label is available from the TXDPS website.
 - 1. The serial number of the instrument
 - 2. The date the instrument was received into the calibration laboratory
 - 3. A list of all visual defects that would prevent the instrument from being calibrated. If no visual defects are noted, enter none on the Instrument Receipt and Condition Notes label.
- B. When received into the calibration laboratory, the instrument should be in proper working order and suitable for calibration. To demonstrate this, the instrument must successfully complete the following and the results for each procedure shall be recorded on the Instrument Receipt and Condition Notes label (OSD-CAL-02). To indicate successful completion, mark the box adjacent to each requirement on the label.
 - 1. To begin the calibration procedure, turn on the instrument. If the instrument is already on, turn it off and then turn it on.
 - 2. The instrument must conduct an air blank.
 - 3. The instrument must then display NOT READY.
 - 4. The instrument must then conduct and pass the Diagnostic Test.
 - 5. The instrument must then display the scrolling message.
- C. The Calibration Analyst shall sign and date the Instrument Receipt and Condition Notes label.
- D. If any of the above cannot be successfully completed, the calibration procedure shall be stopped, the Instrument Receipt and Condition Notes label shall be affixed to an 8.5 x 11 inch sheet of paper and all deficiencies shall be noted on the Calibration Analyst Worksheet (OSD-CAL-04).
- E. An instrument that has been received into the calibration lab that has any visual defects that would prevent the instrument from being calibrated and/or does not successfully complete all of the requirements above shall not be calibrated. All deficiencies shall be noted on the Calibration Analyst Worksheet (OSD-CAL-04) and the instrument shall be repaired before it may be calibrated.



- F. Calibrations must be performed using simulators that are on the Breath Alcohol Laboratory approved simulator list which is available from the TXDPS website.
- G. The nominal reference values 0.000, 0.040, 0.080, 0.150, and 0.400 will be used to perform the calibration. The 0.000 reference material shall consist of purified water. Purified water and all ethanol reference materials used in the calibration will be provided by the OSD.
- H. The OSD shall provide the documents necessary to establish NIST traceability, vapor concentration, nominal value and combined uncertainty of the ethanol reference materials used to perform instrument calibrations. The OSD shall also provide information and documentation on the preparation of purified water used to perform instrument calibrations.

3.3 Conducting the Calibration Procedure

- A. The calibration procedure may be conducted only by a certified Technical Supervisor. The Technical Supervisor conducting the calibration procedure is the Calibration Analyst.
- B. The calibration procedure shall be performed under any of the following conditions:
 - 1. Prior to an instrument being placed into evidential service for the first time.
 - 2. The instrument has undergone a calibration adjustment.
 - 3. As determined by the Technical Supervisor.
- C. In no particular order, the Calibration Analyst shall note the following for each nominal value while conducting the calibration procedure on the Calibration Notes Label (OSD-CAL-03). The Calibration Notes Label is available from the TXDPS website.
 - 1. The serial number of the NIST traceable thermometer.
 - 2. The calibration expiration date of the NIST traceable thermometer.
 - 3. Mark box to indicate that the foil liner was sealed to the solution bottle.
 - 4. The Lot Number of the reference material.
 - 5. The simulator model.
 - 6. The simulator serial number.
 - 7. Ensure the simulator is properly sealed by acknowledging sufficient back pressure when blowing into the inlet port while the outlet port is blocked. Mark the box to indicate that the simulator was sealed.
 - 8. Visually ensure the stirring mechanism is turning. Mark the box to indicate that the simulator stirrer was turning.
 - 9. Before beginning the analysis of each reference solution, ensure that a NIST traceable thermometer in the simulator is reading $34.0 \pm 0.2^{\circ}\text{C}$. Mark box to indicate that the NIST traceable thermometer was reading $34 \pm 0.2^{\circ}\text{C}$.
 - 10. Connect the simulator to the instrument.
 - 11. Conduct twenty sequential calibration checks.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 6 of 19

12. After the analysis of each reference solution, ensure that a NIST traceable thermometer in the simulator is reading $34.0 \pm 0.2^{\circ}\text{C}$. Mark the box to indicate that the NIST traceable thermometer was reading $34 \pm 0.2^{\circ}\text{C}$.
13. List all repairs or calibration adjustments made to the instrument or simulator during the calibration procedure. If no repairs or calibration adjustments were made, enter none.
- D. The Calibration Analyst shall sign and date the Calibration Notes Label.
- E. Affix the following labels to the appropriate Calibration Check Printout.
 1. Affix the Instrument Receipt and Condition Notes label (OSD-CAL-02) to the 0.000 calibration check printed by the instrument.
 2. Affix the appropriate Calibration Notes label (OSD-CAL-03) to each calibration check printed by the instrument.
 3. Affix the label from the reference material bottle to the calibration check printed by the instrument for each reference material analyzed and initial and/or sign the Calibration Check Printout.

4 Instrument Calibration Certificate Workbook

4.1 General

- A. To document the calibration, the Technical Supervisor shall complete OSD-CAL-04, OSD-CAL-05 and OSD-CAL-06 in the most current version of the Instrument Calibration Certificate Workbook (OSD-WBK-01). The Instrument Calibration Certificate Workbook is composed of the Calibration Analyst Worksheet (OSD-CAL-04), the Technical and Administrative Review Checklist (OSD-CAL-05), the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06), the Amended Calibration Analyst Worksheet (OSD-CAL-08), the Amended Technical and Administrative Review Checklist (OSD-CAL-09) and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10). The Workbook is available from the TXDPS website.

4.2 Calibration Analyst Worksheet

- A. The Calibration Analyst Worksheet (OSD-CAL-04) shall be completed by the Calibration Analyst.
- B. The Calibration Analyst is the Technical Supervisor who performed the calibration procedure.
- C. When the Workbook is opened, the Calibration Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Worksheet and the electronic signature of the Calibration Analyst.
- D. After the password has been entered, the Calibration Analyst shall select Begin the Worksheet.
- E. Entries to the Calibration Analyst Worksheet may be made in any order by the Calibration Analyst, and must be completed before forwarding the Workbook to the Reviewing Analyst.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 7 of 19

-
- F. A comment box in each blank in the Calibration Analyst Worksheet gives detailed instructions to the Calibration Analyst about how to complete each entry.
- G. In order to ensure ethanol vapor equilibration between the simulator and instrument, record only the final 15 sequential calibration checks for each nominal value in the Calibration Analyst Worksheet. Instrument results are to be recorded to three digits after the decimal point. Example 0.080 g/210 L
- H. Calibration test results
1. Each of the fifteen analyses of the purified water must be 0.000.
 2. The mean of the fifteen analyses of each ethanol reference solution must be within ± 0.0030 or 3% (whichever is greater) of the vapor concentration of the certified ethanol reference solution. Mean results shall be recorded to four digits (rounded) after the decimal. Example 0.0801 g/210 L
 3. The standard deviation of the nominal 0.040, 0.080 and 0.150 g/210 L certified reference solutions shall be recorded to five digits (rounded) after the decimal and must be less than 0.00100.
 4. The standard deviation of the nominal 0.400 g/210 L certified reference solution shall be recorded to five digits (rounded) after the decimal and must be less than 0.00200.
- I. When the information and the data entered in the Calibration Analyst Worksheet meet all of the required specifications, the Worksheet will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall enter their electronic signature and then save the Workbook.
- J. The Calibration Analyst shall submit the Calibration Workbook, along with all initialed/signed and scanned instrument calibration checks printed by the instrument during calibration to another analyst for technical and administrative review. These documents may be submitted to the Reviewing Analyst by any electronic means other than facsimile transmission.
- K. If at any time during the calibration procedure it becomes necessary to terminate the calibration procedure due to unacceptable results or instrument or equipment in need of adjustment or repair, or for any other reason, all records generated to that point will be retained and the reason for the unsuccessful attempt will be documented on the Calibration Analyst Worksheet. A complete calibration procedure shall be accomplished before a Calibration Certificate may be issued.
1. Indicate the calibration procedure was halted and/or not properly completed by marking the appropriate box or boxes on the Calibration Analyst Worksheet and note the reason(s) the calibration procedure was not properly completed in the space provided.
 2. The Worksheet will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall enter their electronic signature and then save the Workbook.
-



4.3 Technical and Administrative Review Checklist

- A. The Technical and Administrative Review Checklist (OSD-CAL-05) shall be completed by the Reviewing Analyst.
- B. The Reviewing Analyst is the Technical Supervisor who performed the Technical and Administrative Review.
- C. The Reviewing Analyst shall not be the analyst who performed the calibration procedure.
- D. When the Workbook is opened, the Reviewing Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Technical and Administrative Review Checklist and the electronic signature of the Reviewing Analyst.
- E. The Reviewing Analyst shall ensure that the calibration was properly completed and that all of the information entered on the Calibration Analyst Worksheet and all other documents submitted by the Calibration Analyst are correct.
- F. Entries to the Technical and Administrative Review Checklist may be made in any order by the Reviewing Analyst.
- G. A comment box in each blank in the Technical and Administrative Review Checklist gives detailed instructions to the Reviewing Analyst about how to complete each entry.
- H. Discrepancies shall be brought to the attention of the Calibration Analyst and resolution shall take place prior to issuance of the certificate.
 - 1. If the Calibration Analyst determines the discrepancy does not affect the quality of the work, the Calibration Analyst shall make the needed correction and resubmit the Workbook to the Reviewing Analyst for technical and administrative review. Some examples of discrepancies that do not affect the quality of the work include, but are not limited to, typographical errors, and failure to sign/initial a calibration check printout.
 - 2. If the Calibration Analyst determines the discrepancy affects the quality of the work, the Calibration Analyst shall terminate the calibration procedure and note the error on the Calibration Worksheet. Example: A data entry error that when corrected results in the instrument not meeting one or more requirements listed in this document.
- I. When all of the documents submitted by the Calibration Analyst have been reviewed and found to be correct and the Technical and Administrative Review Checklist is properly completed, the Checklist will prompt the Reviewing Analyst to enter their electronic signature. The Reviewing Analyst shall enter their electronic signature and the Evidential Breath Alcohol Testing Instrument Calibration Certificate tab will be revealed.
- J. The Reviewing Analyst shall review the Evidential Breath Alcohol Testing Instrument Calibration Certificate and if it is properly completed, the Reviewing Analyst shall, when prompted, affix their electronic signature to the Calibration Certificate and then save the Workbook.
- K. The Workbook containing the Calibration Analyst Worksheet, the Technical and Administrative Review Checklist and the Evidential Breath Alcohol Testing



Instrument Calibration Certificate shall be returned to the Calibration Analyst who shall issue the Evidential Breath Alcohol Testing Instrument Calibration Certificate. These documents may be returned by any electronic means other than facsimile transmission.

4.4 Evidential Breath Alcohol Testing Instrument Calibration Certificate

- A. The Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) shall be completed and issued by the Calibration Analyst.
- B. The Calibration Analyst who issues the certificate shall be the Technical Supervisor who performed the calibration procedure.
- C. When the Workbook is opened, the Calibration Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Calibration Certificate and the electronic signature of the Calibration Analyst.
- D. A comment box in each blank in the Evidential Breath Alcohol Testing Instrument Calibration Certificate gives detailed instructions to the Calibration Analyst about how to complete each entry.
- E. The Calibration Analyst shall ensure that the calibration was properly completed and that all of the information entered on all of the calibration documents including the Calibration Analyst Worksheet, Technical and Administrative Review Checklist and the Evidential Breath Alcohol Testing Instrument Calibration Certificate is correct.
- F. When the information and the data entered in the Evidential Breath Alcohol Testing Instrument Calibration Certificate meet all of the required specifications, the Calibration Certificate will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall issue the certificate by affixing their electronic signature to the Evidential Breath Alcohol Testing Instrument Calibration Certificate and then save the Workbook.
- G. After the Calibration Analyst issues the Evidential Breath Alcohol Testing Instrument Calibration Certificate, the Workbook and all of the relevant documents generated during the calibration of the instrument shall be emailed to the OSD.
- H. An electronic file for each calibrated instrument shall be maintained by the OSD.

5 Discrepancies Identified After Certificate Issuance

5.1 General

- A. After the certificate has been issued, all discrepancies identified shall be brought to the attention of the Calibration Analyst and the OSD. All other affected parties shall be notified.
- B. Discrepancies may occur in one or more of the following: the Instrument Calibration Certificate Workbook, the sequential calibration check printouts, the Instrument Receipt and Condition Notes (OSD-CAL-02) and/or the Calibration Notes (OSD-CAL-03).



- C. Discrepancy(s) identified after an instrument has been placed into service will be evaluated by the OSD and the validity of the tests conducted on the instrument will be determined.

5.2 Discrepancies Requiring a Supplement to the Calibration Certificate

- A. Discrepancies that do not affect the Instrument Calibration Certificate Workbook can occur in the Instrument Receipt and Condition Notes (OSD-CAL-02), the Calibration Notes (OSD-CAL-03) and the sequential calibration check printouts.
- B. When the Instrument Receipt and Condition Notes, the Calibration Notes and the sequential calibration check printouts are amended to correct a discrepancy(s), all changes and/or additions shall be initialed and dated, and noted and explained in the Supplement to the Calibration Certificate (OSD-CAL-07).

5.3 Discrepancies Requiring a Supplement to the Calibration Certificate and the Completion of an Amended Instrument Calibration Certificate

- A. When a discrepancy occurs in the Instrument Calibration Certificate Workbook, the original Workbook shall not be changed. The Calibration Analyst shall complete and electronically sign a Supplement to the Calibration Certificate (OSD-CAL-07), noting and explaining the discrepancy(s) and complete an Amended Calibration Analyst Worksheet (OSD-CAL-08), an Amended Technical and Administrative Review Checklist (OSD-CAL-09) and an Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10) which are contained in the Instrument Calibration Certificate Workbook (OSD-WBK-01). These forms are available from the TXDPS website.
- B. The Instrument Calibration Certificate Workbook is composed of the Calibration Analyst Worksheet (OSD-CAL-04), the Technical and Administrative Review Checklist (OSD-CAL-05), the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06), the Amended Calibration Analyst Worksheet (OSD-CAL-08), the Amended Technical and Administrative Review Checklist (OSD-CAL-09) and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10).

5.4 Supplement to the Calibration Certificate

- A. When an instrument calibration discrepancy is discovered after the Calibration Certificate has been issued, the Calibration Analyst shall complete a report titled Supplement to the Calibration Certificate (OSD-CAL-07) noting and explaining the discrepancy(s). The Supplement is available from the TXDPS website.
- B. When the Supplement is opened by the Calibration Analyst, the Calibration Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Supplement and the electronic signature of the Calibration Analyst.
- C. A comment box in each blank in the Supplement gives detailed instructions to the Calibration Analyst and the Reviewing Analyst about how to complete each entry.
- D. Entries to the Supplement may be made in any order.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 11 of 19

- E. When the information and the data entered in the Supplement meet all of the required specifications, the Supplement will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall affix their electronic signature to the Supplement and then save the Supplement.
- F. The documents may be submitted to the Reviewing Analyst by any electronic means other than facsimile transmission.
- G. When the Supplement is opened by the Reviewing Analyst, the Reviewing Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Supplement and the electronic signature of the Reviewing Analyst.
- H. When all of the documents submitted by the Calibration Analyst have been reviewed and found to be correct the Supplement will prompt the Reviewing Analyst to enter their electronic signature. The Reviewing Analyst shall enter their electronic signature.
- I. The Supplement shall be returned to the Calibration Analyst by any electronic means other than facsimile transmission.
- J. When the Calibration Analyst receives the Supplement from the Reviewing Analyst, the Calibration Analyst shall review all of the documents and when they are properly completed shall email the Supplement and all other relevant documents generated during the calibration of the instrument to the OSD for inclusion in the instrument's electronic file.

5.5 Amended Calibration Analyst Worksheet

- A. The Amended Calibration Analyst Worksheet (OSD-CAL-08) shall be completed by the Calibration Analyst.
- B. When the Workbook is opened, the Calibration Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Amended Worksheet and the electronic signature of the Calibration Analyst.
- C. After the password has been entered, the Calibration Analyst should select Begin an Amended Worksheet.
- D. Entries to the Amended Calibration Analyst Worksheet may be made in any order by the Calibration Analyst, and must be completed before forwarding the Workbook to the Reviewing Analyst.
- E. A comment box in each blank in the Amended Calibration Analyst Worksheet gives detailed instructions to the Calibration Analyst about how to complete each entry.
- F. In order to ensure ethanol vapor equilibration between the simulator and instrument, record only the final 15 sequential calibration checks for each nominal value in the Amended Calibration Analyst Worksheet. Instrument results are to be recorded to three digits after the decimal point. Example 0.080 g/210 L
- G. Calibration test results
 - 1. Each of the fifteen analyses of the purified water must be 0.000.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 12 of 19

2. The mean of the fifteen analyses of each ethanol reference solution must be within ± 0.0030 or 3%, whichever is greater, of the vapor concentration of the certified reference solution. Mean results shall be recorded to four digits (rounded) after the decimal. Example 0.0801 g/210 L
3. The standard deviation of the nominal 0.040, 0.080 and 0.150 g/210 L certified reference solutions shall be recorded to five digits (rounded) after the decimal and must be less than 0.00100.
4. The standard deviation of the nominal 0.400 g/210 L certified reference solution shall be recorded to five digits (rounded) after the decimal and must be less than 0.00200.
- H. When the information and the data entered in the Amended Calibration Analyst Worksheet meet all of the required specifications, the Amended Worksheet will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall enter their electronic signature and then save the Workbook.
- I. The Calibration Analyst shall submit the Workbook, along with all initialed/signed and scanned instrument calibration checks printed by the instrument during calibration to another analyst for technical and administrative review. These documents may be submitted to the Reviewing Analyst by any electronic means other than facsimile transmission.
- J. If at any time during the calibration procedure it becomes necessary to terminate the calibration procedure due to unacceptable results or instrument or equipment in need of adjustment or repair, or for any other reason, all records generated to that point will be retained and the reason for the unsuccessful attempt will be documented on the Amended Calibration Analyst Worksheet. A complete calibration procedure shall be accomplished before an Amended Calibration Certificate may be issued.
 1. Indicate the calibration procedure was halted and/or not properly completed by marking the appropriate box or boxes on the Amended Calibration Analyst Worksheet and note the reason(s) the calibration procedure was not properly completed in the space provided.
 2. The Worksheet will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall enter their electronic signature and then save the Workbook.

5.6 Amended Technical and Administrative Review Checklist

- A. The Amended Technical and Administrative Review Checklist (OSD-CAL-09) shall be completed by the Reviewing Analyst.
- B. The Reviewing Analyst shall not be the analyst who performed the calibration procedure.
- C. When the Workbook is opened, the Reviewing Analyst will be prompted to enter a password. The password must be at least eight characters in length. The password is used to secure the Amended Technical and Administrative Review Checklist and the electronic signature of the Reviewing Analyst.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 13 of 19

- D. The Reviewing Analyst shall ensure that the calibration was properly completed and that all of the information entered on the Amended Calibration Analyst Worksheet and all other documents submitted by the Calibration Analyst are correct.
- E. Entries to the Amended Technical and Administrative Review Checklist may be made in any order by the Reviewing Analyst.
- F. A comment box in each blank in the Amended Technical and Administrative Review Checklist gives detailed instructions to the Reviewing Analyst about how to complete each entry.
- G. Discrepancies shall be brought to the attention of the Calibration Analyst and resolution shall take place prior to issuance of the certificate.
 - 1. If the Calibration Analyst determines the discrepancy does not affect the quality of the work, the Calibration Analyst shall make the needed correction and resubmit the Workbook to the Reviewing Analyst for technical and administrative review. Some examples of discrepancies that do not affect the quality of the work include, but are not limited to, typographical errors, and failure to sign/initial a calibration check printout.
 - 2. If the Calibration Analyst determines the discrepancy affects the quality of the work, the Calibration Analyst shall terminate the calibration procedure and note the error on the Amended Calibration Worksheet. Example: A data entry error that when corrected results in the instrument not meeting one or more requirements listed in this document.
- H. When all of the documents submitted by the Calibration Analyst have been reviewed and found to be correct and the Amended Technical and Administrative Review Checklist are properly completed, the Amended Checklist will prompt the Reviewing Analyst to enter their electronic signature. The Reviewing Analyst shall enter their electronic signature and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate tab will be revealed.
- I. The Reviewing Analyst shall review the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate and if it is properly completed, the Reviewing Analyst shall, when prompted, affix their electronic signature to the Amended Calibration Certificate and then save the Workbook.
- J. The Workbook containing the Amended Calibration Analyst Worksheet, the Amended Technical and Administrative Review Checklist and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate shall be returned to the Calibration Analyst who shall issue the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate. These documents may be returned by any electronic means other than facsimile transmission.

5.7 Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate

- A. The Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10) shall be completed and issued by the Calibration Analyst.
- B. When the Workbook is opened, the Calibration Analyst will be prompted to enter a password. The password must be at least eight characters in length.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 14 of 19

The password is used to secure the Amended Calibration Certificate and the electronic signature of the Calibration Analyst.

- C. A comment box in each blank in the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate gives detailed instructions to the Calibration Analyst about how to complete each entry.
- D. The Calibration Analyst shall ensure that the calibration was properly completed and that all of the information entered on all of the calibration documents including the Amended Calibration Analyst Worksheet, the Amended Technical and Administrative Review Checklist and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate is correct.
- E. When the information and the data entered in the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate meet all of the required specifications, the Amended Calibration Certificate will prompt the Calibration Analyst to enter their electronic signature. The Calibration Analyst shall issue the certificate by affixing their electronic signature to the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate and then save the Workbook.
- F. After the Calibration Analyst issues the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate, the Workbook and all of the relevant documents generated during the calibration of the instrument shall be emailed to the OSD for inclusion in the instrument's electronic file.

5.8 Non-correctable Discrepancies

- A. When a calibration discrepancy occurs that cannot be corrected, a Supplement to the Calibration Certificate (OSD-CAL-07) shall be produced noting and explaining the discrepancy(s), but an amended certificate shall not be produced. To be certified the instrument must undergo a new calibration.
- B. A comment box in each blank in the Supplement to the Calibration Certificate gives detailed instructions to the Calibration Analyst and Reviewing Analyst about how to complete each entry.
- C. When the Calibration Analyst's part of the Supplement is complete, the Calibration Analyst shall electronically sign the Supplement and submit all of the documents generated during the calibration of the instrument and all other relevant documents to a Reviewing Analyst for technical and administrative review.
- D. The Reviewing Analyst shall review all of the documents submitted and note the review on the Supplement. If the Reviewing Analyst determines that the report and/or any of the documents has not been correctly completed and/or the discrepancy(s) have not been accurately noted and explained, the Reviewing Analyst shall notify the Calibration Analyst and resolution shall take place prior to the issuance of the report.
- E. When the technical and administrative review is complete, the Reviewing Analyst shall electronically sign the Supplement and submit it and all of the other reviewed documents to the Calibration Analyst.
- F. When the Calibration Analyst receives the Supplement from the Reviewing Analyst, the Calibration Analyst shall review all of the documents and when



they are properly completed shall then email the Supplement and all other relevant documents generated during the calibration of the instrument to the OSD for inclusion in the instrument's electronic file.

6 Thermometers Used in the Instrument Calibration Procedure

- A. The purpose of this section is to establish quality assurance guidelines for NIST traceable thermometers used in the instrument calibration procedure.
- B. NIST traceable thermometers are to be maintained in the Technical Supervisor's calibration laboratory which has limited access. Reasonable care should be taken in the handling and storage of NIST thermometers to avoid extreme temperatures, shock or breakage.
- C. NIST traceable thermometers shall be calibrated by an approved vendor and once calibrated are considered to be suitable for use for a period of one year.
 - 1. NIST traceable thermometers shall be submitted to an ISO 17025 accredited laboratory capable of issuing a calibration certificate establishing traceability to a NIST reference standard.
 - 2. To pass the calibration, the thermometer must be accurate to within 0.10°C at 34°C.
 - 3. The calibration certificate generated by the calibration laboratory for each NIST traceable thermometer shall be kept in the **Thermometer File**.
- D. A NIST traceable thermometer that has passed calibration and received a calibration certificate shall be used to verify the proper operational temperatures of simulators used in the instrument calibration procedure.
- E. When placed in a simulator, a NIST traceable thermometer that reads 34.0 ±0.2°C verifies that the solution is at the proper operational temperature and is fit for instrument calibration.

7 Proficiency Testing

- A. Once per calendar year all certified Technical Supervisors will be proficiency tested on their ability to calibrate an evidential breath alcohol testing instrument.
- B. For each proficiency test, an email will be provided to each Technical Supervisor being tested explaining the proficiency procedure, how the proficiency test must be done, how the paperwork documenting the calibration of the instrument must be completed and the date on which the results are due. The results will be recorded on a Microsoft® Excel 2003 or later spreadsheet that will also be emailed to each Technical Supervisor.
- C. The unknown proficiency solutions will be CRMs prepared using the method described in the TXDPS Crime Laboratory Breath Alcohol Certified Reference Materials Standard Operating Procedures and distributed in person, through common carrier or the equivalent.
- D. The unknown proficiency solution shall be analyzed on an Intoxilyzer 5000 that was last calibrated by the Technical Supervisor being proficiency tested and the paperwork documenting the calibration of the instrument must have been completed and sent to the OSD prior to the date and time of the proficiency test.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 16 of 19

- E. The proficiency test will be similar to the calibration procedure. The instrument shall be placed in the ACA mode and the unknown proficiency solution shall be analyzed 20 times. The label from the proficiency solution bottle shall be placed on the 20 sequential proficiency check printouts and the printout shall be signed or initialed by the Technical Supervisor.
- F. The Technical Supervisor's name, the proficiency test number, the date the test was conducted and the last 15 sequential proficiency check results shall be recorded in the provided Microsoft® Excel 2003 or later spreadsheet. The proficiency check results shall be recorded to three digits after the decimal point. The spreadsheet will calculate the mean and standard deviation of the 15 sequential proficiency check results. The mean will be reported to four digits after the decimal (rounded) and the standard deviation will be reported to five digits after the decimal (rounded). The Technical Supervisor shall then print the Microsoft® Excel spreadsheet, sign or initial and date it.
- G. The Technical Supervisor shall then scan the spreadsheet, the 20 sequential proficiency check printout and the last Calibration Certificate (one page certificate only) of the instrument used to take the proficiency test into a single three page pdf document and submit it to the OSD.
- H. To pass the proficiency test, the mean of the last 15 sequential proficiency check results must be within ± 0.0030 or 3%, whichever is greater, of the vapor concentration of the proficiency CRM solution and the standard deviation must be less than 0.00100.
- I. Any Technical Supervisor who fails the first attempt will be sent another unknown proficiency solution and given a new deadline date for reporting the results. Any Technical Supervisor who fails the second attempt will be asked to come to the OSD to demonstrate their ability to calibrate an Intoxilyzer 5000 and for remedial training, if necessary.

8 Receipt and Storage of CRM Solutions and Purified Water Used to Calibrate Evidential Breath Alcohol Testing Instruments

- A. Upon receipt of the CRM solutions and purified water, the bottles shall be stored at moderate temperatures in secured, limited access locations.
- B. The CRM solutions and purified water are valid and approved for use for a period of two years from the date of preparation. CRM solutions and purified water that have expired shall be discarded or retained for training or other non-calibration purposes. The label on all retained expired CRM solutions and purified water shall be crossed out with a permanent marker. Expired solutions shall not be used for evidential breath alcohol instrument calibration and shall be stored separately from unexpired CRM solutions and purified water.

9 Uncertainty of Measurement

9.1 General

- A. The uncertainty budget for breath alcohol instrument calibration describes those components that have been identified as contributing to the overall measurement uncertainty for the instrument calibration. These components include contributions from reference standards, reference materials,



measurement procedure, constants and repeatability. Multiple sources may contribute to a single uncertainty component.

9.2 Uncertainty Budget for Breath Alcohol Instrument Calibration

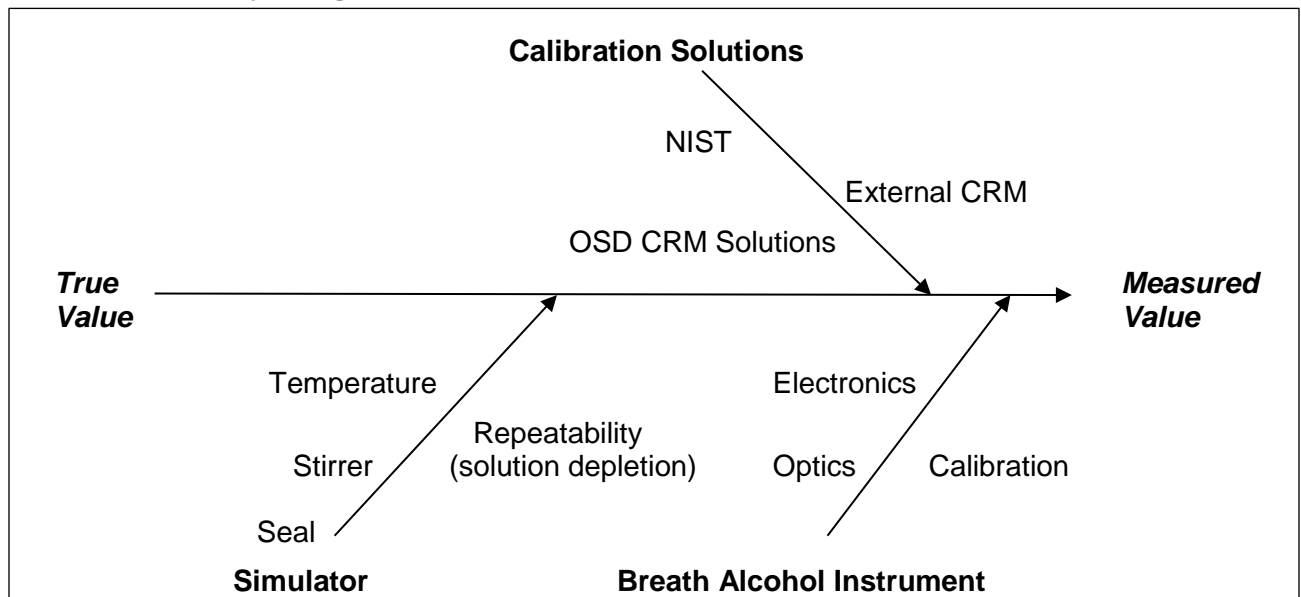


Figure 1: Cause and effect diagram for the calibration of the breath alcohol instrument

9.3 Measurement Uncertainty of Breath Alcohol Instrument Calibration CRMs

A. Uncertainty of Ethanol CRMs

1. Multiple ethanol CRM solutions, obtained from the OSD CRM Laboratory, are analyzed during the calibration of a breath alcohol instrument. The combined uncertainty of each solution, traceable to NIST, is obtained from the solution's Certificate of Analysis. The procedure for estimating the combined uncertainty of OSD CRMs is described in BAL-CRM-07.

B. Uncertainty from Repeatability Measurements

1. The repeatability of breath alcohol instrument measurements is dependent upon multiple factors. These factors can include the simulator temperature, stirrer, and seal; the instrument calibration, optics and electronics; equilibrium between the simulator and the breath alcohol instrument; and depletion of ethanol from the simulator solution from repeated testing and evaporation over time. To minimize solution depletion, the ethanol vapor produced by the simulator is recirculated back into the solution and each solution may only be used for one calibration run of 20 analyses. A calibration run of 20 analyses takes only about 15 minutes and neither the 20 analyses nor the time it takes to complete the run is sufficient to deplete the ethanol in the solution by a significant amount. To ensure equilibrium between the simulator and the breath alcohol instrument, only the last 15 analyses are recorded in the Calibration Analyst Worksheet (OSD-CAL-04). Variations in each of these factors effect repeatability and contribute to uncertainty.
2. This variability of the simulator solution measurements are represented through calculation of the coefficient of variation (CV), from repeated testing of the



simulator solution on a breath alcohol instrument. First the average solution concentration (\bar{X}) is calculated using the following.

$$\bar{X} = \frac{1}{n} \sum_{i=1}^n X_i$$

Where:

\bar{X} = the average simulator solution measurement result

n = the number of measurements (15)

X_i = each individual simulator solution measurement results

i = incremental measurement results, first through last

The standard deviation (SD) of the simulator solution measurements is calculated using the following.

$$SD = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n - 1}}$$

3. The combined uncertainty of a CRM solution ($CV_{Lot\ COA}^2$) is traceable to NIST through an externally prepared CRM obtained from an ISO 17025 accredited provider in a method described in BAL-CRM-07. When used to calibrate an Intoxilyzer, the combined uncertainty of the solution, obtained from the CRM Certificate of Analysis (COA), is represented by the following:

$$CV_{Lot\ COA}^2 = \left(\frac{SD}{\bar{X}} \right)^2$$

4. The uncertainty of a CRM solution as tested on an Intoxilyzer ($CV_{Lot\ Intox}^2$) is calculated using the following equation. The standard deviation of the mean of 15 measurements is used in this equation.

$$CV_{Lot\ Intox}^2 = \left(\frac{SD}{\bar{X}} \right)^2$$

9.4 Calculations and Number Rounding Used in the Instrument Calibration Certificate Workbook

- A. All calculations will be done using Microsoft® Excel 2003 or later. Intoxilyzer results will be recorded to three digits. All values will be rounded to the appropriate number of digits at the completion of the calculation for each formula. Means, vapor concentrations and combined uncertainties will be rounded to four digits. Standard deviations and coefficients of variation will be rounded to five digits.
- B. The formulas used to calculate the combined uncertainty of the Intoxilyzer for each of the four ethanol solutions used to calibrate an Intoxilyzer are detailed below.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Version: 02

Page 19 of 19

1. Eq. 1 is used to calculate the combined Coefficient of Variation (CV_{Comb}) of the Intoxilyzer

$$CV_{Comb} = \sqrt{CV_{Lot\ COA}^2 + CV_{Lot\ Intox}^2} \quad Eq. 1$$

Where:

CV_{Comb} = the combined CV for the ethanol concentration of the CRM solution lot as analyzed by the Intoxilyzer

$CV_{Lot\ COA}$ = the combined CV for the CRM solution lot ($SD_{Comb} \div$ vapor concentration of the CRM solution lot) from the CRM solution lot Certificate of Analysis

$CV_{Lot\ Intox}$ = the CV of the vapor concentration of the CRM solution lot as analyzed on the Intoxilyzer (SD of the CRM solution lot analyzed on the Intoxilyzer \div vapor concentration of the CRM solution lot)

2. Eq.2 is used to calculate the combined standard deviation (SD_{Comb}) of the Intoxilyzer.

$$SD_{Comb} = (CV_{Comb}) (VC_{Lot\ COA}) \quad Eq. 2$$

Where:

SD_{Comb} = the combined standard deviation of the Intoxilyzer. The combined standard deviation (SD_{Comb}) establishes the combined uncertainty of the Intoxilyzer at approximately the 68% confidence level.

$VC_{Lot\ COA}$ = the vapor concentration of the CRM solution lot from its Certificate of Analysis.

3. Eq. 3 is used to calculate the combined uncertainty which is to be reported at the $k = 3$ or approximately the 99.7% confidence level.

$$SD_{Comb} \times 3 = \text{the combined uncertainty for the Intoxilyzer at approximately the 99.7\% confidence level} \quad Eq. 3$$

- C. All of the calculations done in the Instrument Calibration Certificate Workbook (OSD-WBK-01) shall be verified and documented prior to the release of each revision of the Workbook.



Texas Breath Alcohol Testing Program

Office of the Scientific Director

Directive from the Scientific Director

OSD-CAL-01

Preparer

Paul Calderon

Deputy Scientific Director

Date: 09/17/2013

Concurrence

J. Mack Cowan

Scientific Director

Date: 09/20/2013

Version #	Effective Date	Brief Description of Change(s)
00	03/01/2013	Original Issue; Standard Operating Guidelines for Technical Supervisors (1/30/2012)
00a	03/01/2013	Minor revisions- Administrative
01	07/01/2013	Major Revision: Section 2.2, 9.2, 9.3
02	09/27/2013	Major Revision: Section 4.2, 5.5